DADE BEHRING

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OCT 17 2007

510(k) Summary for
Dimension Vista® Protein 3 Calibrator
Dimension Vista® Protein 3 Control
Dimension Vista® Protein 1 Control L
Dimension Vista® Protein 1 Control M
Dimension Vista® Protein 1 Control H

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K072435

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Dade Behring Inc. Marburg GmbH
Emil-von-Behring Str. 76
35041 Marburg, Germany

Contact Information: Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: A. Kathleen Ennis
Tel: 302-631-9352
Fax: 302-631-6299

Preparation date: August 27, 2007

2. **Device Name:** Dimension Vista® Protein 3 Calibrator
Dimension Vista® Protein 3 Control
Dimension Vista® Protein 1 Control L
Dimension Vista® Protein 1 Control M
Dimension Vista® Protein 1 Control H

Classification: Class II; Class I
Product Code: JIX; JJY
Panel: Clinical Chemistry (75)

3. **Identification of the Legally Marketed Device:**

Dimension Vista® Protein 3 Calibrator	K063508
Dimension Vista® Protein 3 Control	K063508
Dimension Vista® Protein 1 Control L	K063663

Dimension Vista® Protein 1 Control M	K063663
Dimension Vista® Protein 1 Control H	K063663

4. Device Descriptions:

Dimension Vista® Protein 3 Calibrator

PROT3 CAL is a multi-analyte, lyophilized, polygeline based product containing urinary α_1-microglobulin, cystatin C and serum albumin of human origin.

Dimension Vista® Protein 3 Control

PROT3 CON is a multi-analyte, low level lyophilized, polygeline and rabbit albumin based product containing urinary α_1 -microglobulin and serum albumin of human origin.

Dimension Vista® Protein 1 Control L

Protein 1 Control L is a multi-analyte, low level liquid human serum based product containing:

α_1-acid glycoprotein	immunoglobulin E
α_1-antitrypsin	immunoglobulin G
C3 complement	immunoglobulin M
C4 complement	prealbumin
ceruloplasmin	soluble transferrin receptor
haptoglobin	albumin
homocysteine	transferrin
immunoglobulin A	

Dimension Vista® Protein 1 Control M and Dimension Vista® Protein 1 Control H

Protein 1 Control M and H are multi-analyte, mid and high level respectively, liquid human serum based products containing:

α_1-acid glycoprotein	immunoglobulin A
α_1-antitrypsin	immunoglobulin E
β_2-microglobulin	immunoglobulin G
C3 complement	immunoglobulin M
C4 complement	prealbumin
ceruloplasmin	soluble transferrin receptor
haptoglobin	albumin
homocysteine	transferrin

5. Device Intended Uses:

Dimension Vista® Protein 3 Calibrator

PROT3 CAL is an *in vitro* diagnostic product for the calibration of the Dimension Vista® System for the α_1 -Microglobulin (A1MIC), Cystatin C(CYSC), Microalbumin (MALB) and specialty Albumin (sALB)* methods.

* For serum, plasma and cerebrospinal fluid

Dimension Vista® Protein 3 Control

PROT3 CON is an assayed intralaboratory quality control, for assessment of precision and analytical bias in the determination of α_1-Microglobulin (A1MIC), specialty Albumin (sAlb)** and Microalbumin (MALB) on the Dimension Vista® System.

** For cerebrospinal fluid (CSF)

Dimension Vista® Protein 1 Control L

PROT1 CON L is an assayed, low level, intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of:

α_1-Acid Glycoprotein (A1AG)
α_1-Antitrypsin (A1AT)
C3 Complement (C3)
C4 Complement (C4)
Ceruloplasmin (CER)
Haptoglobin (HAPT)
Homocysteine (HCYS)
Immunoglobulin A (IGA)
Immunoglobulin E (IGE)
Immunoglobulin G (IGG)
Immunoglobulin M (IGM)
Prealbumin (PREALB)
soluble Transferrin Receptor (sTFR)
specialty Albumin (sALB)***
Transferrin (TRF)

Dimension Vista® Protein 1 Control M and Dimension Vista® Protein 1 Control H

PROT1 CON M and PROT1 CON H are assayed, mid-level and high level respectively, intralaboratory quality controls for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of:

α_1-Acid Glycoprotein (A1AG)	Immunoglobulin A (IGA)
α_1-Antitrypsin (A1AT)	Immunoglobulin E (IGE)
β_2-Microglobulin (B2MIC)	Immunoglobulin G (IGG)
C3 Complement (C3)	Immunoglobulin M (IGM)
C4 Complement (C4)	Prealbumin (PREALB)
Ceruloplasmin (CER)	specialty Albumin (sALB)***
Haptoglobin (HAPT)	soluble Transferrin Receptor (STFR)
Homocysteine (HCYS)	Transferrin (TRF)

*** For serum and plasma

6. Medical device to which equivalence is claimed and comparison information:

Dimension Vista® Protein 3 Calibrator and Dimension Vista® Protein 3 Control modified to include specialty Albumin (sALB), are substantially equivalent in intended use to the current Dimension Vista® Protein 3 Calibrator and Dimension Vista® Protein 3 Control (K063508). The modified Protein 3 Calibrator and Protein 3 Control, like the current products, are intended to be used for the calibration of human protein assays and for use as assayed intralaboratory quality controls respectively, on the Dimension® Vista System.

Dimension Vista® Protein 1 Control L, Dimension Vista® Protein 1 Control M and Dimension Vista® Protein 1 Control H modified to include specialty Albumin (sALB), are substantially equivalent in intended use to the current Dimension Vista® Protein 1 Control L, Dimension Vista® Protein 1 Control M and Dimension Vista® Protein 1 Control H (K063663). Modified Protein 1 Control L, M, and H, like the current products, are intended to be used as assayed intralaboratory quality controls on the Dimension® Vista System.

7. Conclusion

The modified Dimension Vista® Protein 3 Calibrator, Dimension Vista® Protein 3 Control and Dimension Vista® Protein 1 Control L, Dimension Vista® Protein 1 Control M and Dimension Vista® Protein 1 Control H, are substantially equivalent to the legally marketed devices based on the information described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dade Behring Inc.
c\o Ms. A. Kathleen Ennis
Sr. Regulatory Affairs & Compliance Spec.
500 GBC Drive, MS 514, P.O. Box 6101
Newark, DE 19714-6101

OCT 17 2007

Re: k072435
Trade Name: Dimension Vista® Protein 3 Calibrator,
Dimension Vista® Protein 3 Control, Dimension Vista® Protein 3 Control L,
Dimension Vista® Protein 3 Control M, Dimension Vista® Protein 3 Control H
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX, JJY
Dated: August 28, 2007
Received: August 30, 2007

Dear Ms. Ennis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: Dimension Vista® Protein 3 Calibrator

Indications for Use:

Dimension Vista® Protein 3 Calibrator
PROT3 CAL is an *in vitro* diagnostic product for the calibration of the Dimension Vista® System for the α_1-Microglobulin (A1MIC), Cystatin C (CYSC), Microalbumin (MALB) and specialty Albumin (sALB)* methods.

* For serum, plasma and cerebrospinal fluid

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____ (21 CFR 801)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

k072435

Indications Statement

Device Name: Dimension Vista® Protein 3 Control

Indications for Use:

Dimension Vista® Protein 3 Control
Intended Use
PROT3 CON is an assayed intralaboratory quality control, for assessment of precision and analytical bias in the determination of α_1-Microglobulin (A1MIC), specialty Albumin (sALB)[1] and Microalbumin (MALB) on the Dimension Vista® System.

[1] For cerebrospinal fluid (CSF)

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____ (21 CFR 801)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K072435

Indications Statement

Device Name: Dimension Vista® Protein 1 Control L

Indications for Use:

Dimension Vista® Protein 1 Control L
PROT1 CON L is an assayed, low level, intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of:

- α_1-Acid Glycoprotein (A1AG)
- α_1-Antitrypsin (A1AT)
- C3 Complement (C3)
- C4 Complement (C4)
- Ceruloplasmin (CER)
- Haptoglobin (HAPT)
- Homocysteine (HCYS)
- Immunoglobulin A (IGA)
- Immunoglobulin E (IGE)
- Immunoglobulin G (IGG)
- Immunoglobulin M (IGM)
- Prealbumin (PREALB)
- specialty Albumin* (sALB)
- soluble Transferrin Receptor (STFR)
- Transferrin (TRF)

*For serum and plasma

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____ (21 CFR 801)

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510(k) K072435

Indications Statement

Device Name: Dimension Vista® Protein 1 Control M

Indications for Use:

Dimension Vista® Protein 1 Control M
PROT1 CON M is an assayed, mid-level, intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of:

α_1-Acid Glycoprotein (A1AG)	Immunoglobulin A (IGA)
α_1-Antitrypsin (A1AT)	Immunoglobulin E (IGE)
β_2- Microglobulin (B2MIC)	Immunoglobulin G (IGG)
C3 Complement (C3)	Immunoglobulin M (IGM)
C4 Complement (C4)	Prealbumin (PREALB)
Ceruloplasmin (CER)	specialty Albumin* (sALB)
Haptoglobin (HAPT)	soluble Transferrin Receptor (STFR)
Homocysteine (HCYS)	Transferrin (TRF)

*For serum and plasma

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____ (21 CFR 801)

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K073435

Dade Behring Inc.
Dimension Vista® Protein 3 Calibrator
Dimension Vista® Protein 3 Control
Dimension Vista® Protein 1 Control L, M, H
510(k) Notification

Indications Statement

Device Name: Dimension Vista® Protein 1 Control H

Indications for Use:

Dimension Vista® Protein 1 Control H
PROT1 CON H is an assayed, high level, intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of:

α_1-Acid Glycoprotein (A1AG)	Immunoglobulin A (IGA)
α_1-Antitrypsin (A1AT)	Immunoglobulin E (IGE)
β_2- Microglobulin (B2MIC)	Immunoglobulin G (IGG)
C3 Complement (C3)	Immunoglobulin M (IGM)
C4 Complement (C4)	Prealbumin (PREALB)
Ceruloplasmin (CER)	specialty Albumin* (sALB)
Haptoglobin (HAPT)	soluble Transferrin Receptor (STFR)
Homocysteine (HCYS)	Transferrin (TRF)

*For serum and plasma

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____ (21 CFR 801)

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